Legislation/Regulation /Guideline	Scope	Relevant topic covered	Relevant articles	Status
UN 				
United Nations. Universal Declaration of Human Rights, Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948.	Universal human rights	Foundation of bioethical principles	Article 12 Privacy Article 18 Freedom of thought Article 19 Freedom of opinion	Declaration
UNESCO 				
UNESCO United Nations Educational Scientific and Cultural Organization, Universal Declaration on Bioethics and Human Rights, 2005.	Universal human rights and bioethics	Bioethical principles	Principles Art. 3 Human dignity, Art. 4 benefit and harm, Art. 5 autonomy and individual responsibility, Art. 6 consent, Art. 7 persons without capacity to consent, Art. 8 Respect for human vulnerability and personal integrity, Article 9 Privacy and confidentiality, Article 11 Non-discrimination and non-stigmatization, Article 15 Sharing of benefits, Article 18 Decision-making and addressing bioethical issues, Article 19 Ethics committees	Declaration with instruction to implement. (States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.)

UNESCO United Nations Educational Scientific and Cultural Organization, International Declaration on Human Genetic Data, 2003.	The aims of the Declaration are: to ensure the respect of and protection of human rights and freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived.	Obtaining, using and storing of human genetic and proteomic data	General provisions, obtaining, use, storage etc.	Declaration with implementation instruction
UNESCO United Nations Educational Scientific and Cultural Organization, Universal Declaration on the Human Genome and Human Rights, 1997.	Proclaims the ethical principles of research and application of human genome information	Human genome	A. Human dignity and the human genome, B. Rights of the persons concerned, C. Research on the human genome, D. Conditions for the exercise of scientific activity, E. Solidarity and international co-operation	Declaration with instruction to promote the principles
Council of Europe 				
Convention for the Protection Human Rights and Fundamental Freedoms of the Council of Europe, 1950.	Human rights	Foundation of bioethical principles	Article 8 – Right to respect for private and family life, Article 9 – Freedom of thought, conscience and religion, Article 10 – Freedom of expression, Article 14 – Prohibition of discrimination and so on.	Signed and ratified by almost all countries of establishment of BNE partners. For current status see the website.
Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine:	Convention: The Convention as sets out to provide a common framework for the protection of human rights and human dignity	Informed Consent Incompetent subjects Prohibition of financial gain Information which is predictive of genetic disease Confidentiality and right to information	Article 2 – Primacy of the human being, Article 4 – Professional standards, Chapter II – Consent, Article 6 – Protection of persons not able to consent, Article 7 – Protection of persons who have a mental disorder,	For current status see the website. Exceptions (to signature and ratification): • Austria, however Austrian

Convention on Human Rights and Biomedicine, Oviedo, 1997.	in both longstanding and developing areas concerning the application of biology and medicine.		Article 9 – Previously expressed wishes, Chapter III – Private life and right to information Article 10 – Private life and right to information, Chapter IV – Human genome, Chapter V – Scientific research, Chapter VII – Prohibition of financial gain and disposal of a part of the human body, Article 21 – Prohibition of financial gain, Article 22 – Disposal of a removed part of the human body	Bioethics Commission at the Federal Chancellery has advised to ratify the Convention as soon as possible; • Germany; • United Kingdom.
Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Strasbourg. 2002.	Does not apply to organ donation for research purposes. Certain parallels with regard to Brain Banking can be recognized.			The same as Convention on Human Rights and Biomedicine
Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg. 2005.	Protocol covers the full range of research activities in the health field involving interventions on human beings. Does not apply to interventions on deceased donors.			The same as Convention on Human Rights and Biomedicine
Council of Europe Committee of Ministers, Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. In: 2005.	Explanatory report contains explanations and clarifications to the Protocol			Memorandum

Recommendation on research on biological materials of human origin adopted by the Committee of Ministers of the Council of Europe;	Recommendation sets out to give guidance to the committee of ministers with regard to future legislation on biobanks for research purposes as well as other collections of biological material.	Informed Consent Identifiably of the Biological Material and Protection of Personal Data Management of collections of the biological materials	Almost all	Recommendation has been adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies.
CDBI of Council of Europe, Draft explanatory memorandum to the draft recommendation on research on biological materials of human origin, Strasbourg. In: 2006.	Explanatory memorandum contains explanations and clarifications to the Recommendation			Memorandum
Recommendation No R(99)3 of the Committee of Ministers to member states on the harmonization of medico-legal autopsy rules	Harmonization of the medico-legal autopsy rules in the member states	Gives detailed guidelines on how to conduct autopsy	The principles of good conduct of autopsy.	Adopted by the Committee of Ministers on 2 February 1999 at the 658th meeting of the Minister Deputies, with reservations by Netherlands and Germany.
Recommendation No R(99)4 of the Committee of Ministers to member States on principles concerning the legal protection of incapable adults	Recommendation states the principles that should apply to the protection of adults who are incapable of making in an autonomous was decisions concerning any r all of their personal or economic affairs or understand expressing or acting upon such decisions and who consequently cannot protect their interests.	Contains principles which should apply to the measures of protection or other legal arrangements enabling incompetent adults to benefit from representation or assistance.	Principles with regard to protection of incompetent adults.	Adopted by the Committee of Ministers on 23 February 1999 at the 660th meeting of the Minister's Deputies, with reservation by France on principle 23 par. 3.

EC 				
Directive of the EC 95/46/EC on protection of individuals with regard to processing of personal data and free movement of such data;	The directive regulates the processing of personal data. The directive is implemented in national legislation of all BNE partner countries. In particular data protection directive concerns processing of identifiable data of living natural persons, such as patients, registered donors, the surviving family of the deceased donor and so on.	Principles of data protections Rights of the data subjects. Requirements to the processors of data. Duty to notify supervisory authorities.	See extraction: Link	For status see the website. Implemented in national legislation of all BNE partners.
Directive of the EC 98/44/EC on the legal protection of the biotechnological inventions	The directive aims to harmonize the laws of EU member states regarding the patentability of biotechnological inventions, including human genes and set out the limits to patentability of certain subject.		IN particular paragraph 26, the role of informed consent in patentability of the inventions based in biological material of human origin	At the last review by the EC, the directive has been implemented in national legislation of all BNE partner countries.
World Medical Association				

				
World Medical Association, The International Code of Medical Ethics; Declaration of Geneva, 1949.	WMA is made up and funded by medical associations representing medical doctors all over the world. The World Medical Association neither has nor seeks to have actual powers. However Declarations and Statements produced by WMA over the years have carried great weight in national and international debates.	Duties of physician in general and duties of physician to the patient	Different provisions. In particular obligations to reserve absolute confidentiality on all the physician knows about his patient even after the patient has died.	Professional guideline
World Medical Association, World Medical Association Declaration on the Rights of the Patient, 1981.		Declaration of patient rights	Art. 1 Right to medical care of good quality, Art. 3 Right to self-determination, Artt. 4 and 5 The unconscious and legally incompetent patients, Art. 7 right to confidentiality	Professional guideline
World Medical Association, The World Medical Association Declaration on Ethical Consideration Regarding Health Databases, 2002.		Rights of and obligations to the patients with regard to their data included in health databases.	Responsibilities of physician with regard to data of their patients stored in databases.	Professional guideline
World Medical Association, World Medical Association Statement on Patient Advocacy and Confidentiality, 2003.	Recommendation on how to deal with conflicts in advocacy and confidentiality	Breach of confidentiality	Ethical obligation to disclose confidential information	Professional guideline

World Medical Association, The World Medical Association Statement Concerning The Relationship Between Physicians and Commercial Enterprises, 2004.	Guidelines on how to deal with conflicts of interest which may arise from relationship between physician and commercial entity		Section C Gifts, Section D Research funded by a commercial entity; Section E Affiliation with a commercial entity such as consulting or membership on an advisory board	Professional guideline
World Medical Association, The World Medical Association Statement on Genetics and Medicine, 2005.	Statement in order to address some of the concerns raised by genetic technologies and provide guidance to physicians. These guidelines should be updated in accordance with developments in the field of genetics.		Genetic testing, Genetic counseling, confidentiality of results	Professional guideline
World Health Organization 				
World Health Organization, Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research; Scientific and Ethical Review Group (SERG) of WHO. In: 2007.	This Guideline has been drawn up to assist researchers in dealing with the ethical issues relating to how clinical research materials are obtained, used and eventually disposed of, and the corresponding informed consent requirements.		The guideline is intended for the future collection of samples, many of the ethical considerations are relevant also to previously collected human biological materials stored in repositories.	Guideline

Jurisprudence (cases)			
John Moore v. California Regents (UCLA), 1990.	American case, which had great impact on the debate of property in human tissue.	Moore's spleen tissue, removed during routine treatment for hairy cell leukemia at UCLA, has been used to derive immortal cell line, capable of producing a variety of valuable products. The UCLA applied and was granted a patent on the cell line. Accidentally informed of this, Moore has filed a law suit accusing UCLA of wrongfully taking and retaining his property (spleen cells) and claiming the interest on his property. The defendants argued that Moore's spleen was medical waist and Moore had left it to UCLA to be disposed of. The Supreme Court of the US has ruled that Moore's physician should have disclosed his financial interest in using his patient's spleen, but denied Moore's claim of property and interest in his cells after they have been removed from his body.	
Canavan case (Greenberg v. Maimi Children's Hospital) 2003	American case, which had great impact on the debate of property of human tissue.	Families affected by Canavan desease (leukodystrophy and spongy degeneration of the brain), have actively supported research into the genes responsible for this disease. The "Cananvan families" have been actively recruiting and registering donors, donating money, biological, samples and medical records for research, with the goal of developing a widely accessible and affordable genetic test. Researcher engaged by the "Canavan families" has successfully identified the gene and developed tests for the disease. Without the knowledge of the Canavan families he has patented the sequence, thereby securing the intellectual property rights of Maimi children's hospital an organization by which he has been employed. The Canavan families, who found that patent rights were used for the purposes unintended by them (economic benefit of researcher and his organization), filed a law suit claiming the property of samples and interest in the property. The judge dismissed all claims, while drawing a distinction in commercializing human tissue as opposed to commercializing the results of research. The case was never brought before a higher court since the parties have agreed upon a settlement, the details of which have never been publicized.	
Washington University v. Catalona. 2007	American case concerning informed consent and the gift of research samples to a certain party.	Dr. Catalona who decided to leave his employer Washington University, has intended to take "his" tissue samples with him. The samples where collected from patients who have signed consent forms authorizing the use of tissue for research. Dr. Catalona however had send 10.000 letters to the donors of the tissue asking to donate this tissue to him personally. Washington University disagreed with Catalona's conduct and claimed the ownership of the samples. The judge ruled that unconditional gift was made by the donors to the	

		University, not to Dr. Catalona. This decision was based upon the fact that consents where signed on the Washington University forms, the patients where referred for questions to university personnel and that the university paid and controlled the storage and the use of samples.		